

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

To: STEPHEN FINCH
GROSSMAN, TUCKER, PERREAULT &
PFLEGER, PLLC
55 SO. COMMERCIAL ST.
MANCHESTER, NH 03101

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL SEARCH REPORT AND
THE WRITTEN OPINION OF THE INTERNATIONAL
SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

RECEIVED

APR 26 2010

Applicant's or agent's file reference

ART049PCT

International application No.

PCT/US2010/025095

Date of mailing
(day/month/year)

FOR FURTHER ACTION See paragraphs 1 and 4 below

International filing date
(day/month/year)

23 February 2010

Applicant

ARTHROSURFACE INCORPORATED

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes
1211 Geneva 20, Switzerland, Facsimile No.: +41 22 338 82 70

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ **With regard to the protest against payment of (an) additional fee(s) under Rule 40.2,** the applicant is notified that:

☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. Reminders

Shortly after the expiration of **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90bis.1 and 90bis.3, respectively, before the completion of the technical preparations for international publication.

The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450
Facsimile No. 571-273-3201

Authorized officer:

Blaine R. Copenheaver

Telephone No. 571-272-7774

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

To: STEPHEN FINCH
GROSSMAN, TUCKER, PERREAULT &
PFLEGER, PLLC
55 SO. COMMERCIAL ST.
MANCHESTER, NH 03101

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL SEARCH REPORT AND
THE WRITTEN OPINION OF THE INTERNATIONAL
SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

Date of mailing
(day/month/year)

21 APR 2010

Applicant's or agent's file reference

ART049PCT

FOR FURTHER ACTION See paragraphs 1 and 4 below

International application No.

PCT/US2010/025095

International filing date

(day/month/year)

23 February 2010

Applicant

ARTHROSURFACE INCORPORATED

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Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes
1211 Geneva 20, Switzerland, Facsimile No.: +41 22 338 82 70

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

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☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

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The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

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In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450
Facsimile No. 571-273-3201

Authorized officer:

Blaine R. Copenheaver

Telephone No. 571-272-7774

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference ART049PCT	FOR FURTHER ACTION		see Form PCT/ISA/220 as well as, where applicable, item 5 below.
International application No. PCT/US2010/025095	International filing date <i>(day/month/year)</i> 23 February 2010	(Earliest) Priority Date <i>(day/month/year)</i> 23 February 2009	
Applicant ARTHROSURFACE INCORPORATED			

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 2 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the language, the international search was carried out on the basis of:

- ☒ the international application in the language in which it was filed.
☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

b. ☐ This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6bis(a)).

c. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☐ **Certain claims were found unsearchable** (see Box No. II).

3. ☐ **Unity of invention is lacking** (see Box No. III).

4. With regard to the title,

- ☒ the text is approved as submitted by the applicant.
☐ the text has been established by this Authority to read as follows:

5. With regard to the abstract,

- ☒ the text is approved as submitted by the applicant.
☐ the text has been established, according to Rule 38.2, by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the drawings,

- a. the figure of the **drawings** to be published with the abstract is Figure No. _____
☐ as suggested by the applicant.
☐ as selected by this Authority, because the applicant failed to suggest a figure.
☐ as selected by this Authority, because this figure better characterizes the invention.
- b. ☒ none of the figures is to be published with the abstract.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2010/025095

A. CLASSIFICATION OF SUBJECT MATTER

IPC(8) - A61F 2/38 (2010.01)

USPC - 623/20.14

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC(8) - A61F 2/38, 2/30 (2010.01)

USPC - 623/18.11,20.14,20.16,20.17,23.72,23.73,23.74,14.12,13.17,23.63,23.76,23.75; 606/77,76

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

USPTO EAST System (US, USPG-PUB, EPO, DERWENT), PatBase

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 6,679,917 B2 (EK) 20 January 2004 (20.01.2004) entire document	1-18
Y	US 2004/0167632 A1 (WEN et al) 26 August 2004 (26.08.2004) entire document	1-8
Y	US 2007/0038307 A1 (WEBSTER et al) 15 February 2007 (15.02.2007) entire document	9-15
Y	US 2004/0210309 A1 (DENZER et al) 21 October 2004 (21.10.2004) entire document	16-18
Y	US 7,361,195 B2 (SCHWARTZ et al) 22 April 2008 (22.04.2008) entire document	3, 4, 6, 7, 10-15
A	US 6,626,950 B2 (BROWN et al) 30 September 2003 (30.09.2003) entire document	1-18
A	US 2004/0220574 A1 (PELO et al) 04 November 2004 (04.11.2004) entire document	1-18

☐ Further documents are listed in the continuation of Box C.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

08 April 2010

Date of mailing of the international search report

21 APR 2010

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US, Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450

Facsimile No. 571-273-3201

Authorized officer:

Blaine R. Copenheaver

PCT Helpdesk: 571-272-4300

PCT OSP: 571-272-7774

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To: STEPHEN FINCH
GROSSMAN, TUCKER, PERREAULT &
PFLEGER, PLLC
55 SO. COMMERCIAL ST.
MANCHESTER, NH 03101

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing
(day/month/year)

21 APR 2010

Applicant's or agent's file reference
ART049PCT

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/US2010/025095

International filing date (day/month/year)

23 February 2010

Priority date (day/month/year)

23 February 2009

International Patent Classification (IPC) or both national classification and IPC

IPC(8) - A61F 2/38 (2010.01)

USPC - 623/20.14

Applicant **ARTHROSURFACE INCORPORATED**

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/US
Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450
Facsimile No. **571-273-3201**

Date of completion of this opinion

08 April 2010

Authorized officer:

Blaine R. Copenheaver

PCT Helpdesk: 571-272-4300
PCT OSP: 571-272-7774

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US2010/025095

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:
 - ☒ the international application in the language in which it was filed.
 - ☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).
2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))
3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing filed or furnished:
 - a. (means)
 - ☐ on paper
 - ☐ in electronic form
 - b. (time)
 - ☐ in the international application as filed
 - ☐ together with the international application in electronic form
 - ☐ subsequently to this Authority for the purposes of search
4. ☐ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
5. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US2010/025095

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-18	YES
	Claims	None	NO
Inventive step (IS)	Claims	None	YES
	Claims	1-18	NO
Industrial applicability (IA)	Claims	1-18	YES
	Claims	None	NO

2. Citations and explanations:

Claims 1, 2, 5 and 8 lack an inventive step under PCT Article 33(3) as being obvious over Ek in view of Wen et al.

Referring to claim 1, Ek discloses a joint prosthesis (40) (Abstract; Fig. 1) comprising: a first surface (42) having a curvature that substantially matches the contour of native articular surface (col. 13, lines 16-29; Figs. 1, 4a-4c, 5a, 5b), said first surface comprising a cobalt chromium alloy (col. 25, lines 13-17); and said first surface including a plurality of features (43) (Fig. 4c). However, Ek does not show a prosthesis comprising: an average surface feature size of between 10 and 30 nm. However, Wen et al. teaches a prosthesis (Abstract) comprising: a surface having a nanoscale feature size (paragraphs [0050], [0058]) for the purpose of facilitating acceptance of tissue and bone growth or apposition after implantation (Abstract). Therefore, it would be obvious to one of ordinary skill in the art at the time of invention to modify the invention of Ek to include a prosthesis comprising: an average surface feature size of between 10 and 30 nm for the purpose of providing adequate adherence between a bioactive coating and an implant, facilitating acceptance of tissue and bone growth or apposition after implantation and since such a modification would involve a mere change in the size of a component.

Referring to claim 2, Ek discloses that as applied to claim 1. However, Ek does not show a prosthesis wherein the first surface comprises features that are substantially spherical and about 20 nm in size. However, Wen et al. teaches a prosthesis (Abstract) comprising: a surface having a nanoscale feature size (paragraphs [0050], [0058]) for the purpose of facilitating acceptance of tissue and bone growth or apposition after implantation (Abstract). It would be obvious to one of ordinary skill in the art at the time of invention to modify the invention of Ek to include a prosthesis wherein the first surface comprises features that are substantially spherical and about 20 nm in size for the purpose of providing adequate adherence between a bioactive coating and an implant, facilitating acceptance of tissue and bone growth or apposition after implantation and since such a modification would involve a mere change in the size of a component and since a change in shape of an element involves only routine skill in the art.

Referring to claim 5, Ek discloses that as applied to claim 1. Ek further discloses a prosthesis wherein the prosthesis is affixed to bone tissue in a human patient (Fig. 1).

Referring to claim 8, Ek discloses that as applied to claim 1. Ek further discloses a prosthesis wherein the prosthesis is a knee prosthesis (Fig. 1).

Claim 9 lacks an inventive step under PCT Article 33(3) as being obvious over Ek in view of Webster et al.

Referring to claim 9, Ek discloses a prosthesis (40) for supporting the growth of mammalian cells (Abstract; col. 13, lines 54-60; Fig. 1), the prosthesis comprising a cobalt chromium alloy surface (42) (col. 13, lines 16-29; col. 25, lines 13-17; Figs. 1, 4a-4c, 5a, 5b). However, Ek does not show a prosthesis comprising a surface energy of greater than 30mJ/m². However, Webster et al. teaches a prosthesis (Abstract) comprising a surface energy of greater than 30mJ/m² (paragraphs [0048], [0049]). Therefore, it would be obvious to one of ordinary skill in the art at the time of invention to modify the invention of Ek to include a prosthesis comprising a surface energy of greater than 30mJ/m² as taught by Webster et al. for the purpose of increasing the implants bonding strength.

Claims 16-18 lack an inventive step under PCT Article 33(3) as being obvious over Ek in view of Denzer et al.

Referring to claim 16, Ek discloses a prosthesis (40) for supporting mammalian cells (Abstract; Fig. 1), the prosthesis comprising a contoured surface (42) comprising a cobalt chromium alloy (col. 13, lines 16-29; col. 25, lines 13-17; Figs. 1, 4a-4c, 5a, 5b). However, Ek does not show a prosthesis comprising a wet contact angle of less than about 60 degrees. However, Denzer et al. teaches a prosthesis (Abstract) comprising a wet contact angle of less than about 60 degrees (paragraphs [0006], [0018], [0030]). Therefore, it would be obvious to one of ordinary skill in the art at the time of invention to modify the invention of Ek to include a prosthesis comprising a wet contact angle of less than about 60 degrees as taught by Denzer et al. for the purpose of improving the osteointegration properties of the implant.

Referring to claim 17, Ek discloses that as applied to claim 16. However, Ek does not show a prosthesis wherein the wet contact angle is less than about 45 degrees. However, Denzer et al. teaches a prosthesis wherein the wet contact angle is less than about 45 degrees (paragraphs [0006], [0018], [0030]). Therefore, it would be obvious to one of ordinary skill in the art at the time of invention to modify the invention of Ek to include a prosthesis wherein the wet contact angle is less than about 45 degrees as taught by Denzer et al. for the purpose of improving the osteointegration properties of the implant.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US2010/025095

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

Referring to claim 18, Ek discloses that as applied to claim 16. However, Ek does not show a prosthesis wherein the wet contact angle is less than about 45 degrees. However, Denzer et al. teaches a prosthesis wherein the wet contact angle is less than about 20 degrees (paragraphs [0006], [0018], [0030]). Therefore, it would be obvious to one of ordinary skill in the art at the time of invention to modify the invention of Ek to include a prosthesis wherein the wet contact angle is less than about 45 degrees as taught by Denzer et al. for the purpose of improving the osteointegration properties of the implant.

Claims 3, 4, 6 and 7 lack an inventive step under PCT Article 33(3) as being obvious over Ek in view of Wen et al. in view of Schwartz et al.

Referring to claim 3, Ek in view of Wen et al. discloses that as applied to claim 1. However, Ek in view of Wen et al. does not show a prosthesis further comprising a layer of mammalian cells on a first surface. However, Schwartz et al. teaches a prosthesis (22) (Abstract; Fig. 4) further comprising a layer of mammalian cells (chondrocytes embedded in 28) on a first surface (lower 22) (col. 8, lines 41-48; col. 12, lines 29-60; Fig. 4). Therefore, it would be obvious to one of ordinary skill in the art at the time of invention to modify the invention of Ek in view of Wen et al. to include a prosthesis further comprising a layer of mammalian cells on a first surface as taught by Schwartz et al. for the purpose of expediting the healing of damaged cartilage.

Referring to claim 4, Ek in view of Wen et al. discloses that as applied to claim 1. However, Ek in view of Wen et al. does not show a prosthesis further comprising a layer of human chondrocytes on a first surface. However, Schwartz et al. teaches a prosthesis (22) (Abstract; Fig. 4) further comprising a layer of human chondrocytes (embedded in 28) on a first surface (lower 22) (col. 2, lines 6-12; col. 8, lines 41-48; col. 12, lines 29-60; Fig. 4). Therefore, it would be obvious to one of ordinary skill in the art at the time of invention to modify the invention of Ek in view of Wen et al. to include a prosthesis further comprising a layer of human chondrocytes on a first surface as taught by Schwartz et al. for the purpose of expediting the healing of damaged cartilage.

Referring to claim 6, Ek in view of Wen et al. discloses that as applied to claim 1. However, Ek in view of Wen et al. does not show a prosthesis wherein human cartilage is affixed to a first surface. However, Schwartz et al. teaches a prosthesis (22) (Abstract; Fig. 4) wherein human cartilage is affixed to a first surface (lower 22) (col. 2, lines 6-12; col. 8, lines 41-48; col. 12, lines 29-60; Fig. 4). Therefore, it would be obvious to one of ordinary skill in the art at the time of invention to modify the invention of Ek in view of Wen et al. to include a prosthesis wherein human cartilage is affixed to a first surface as taught by Schwartz et al. for the purpose of expediting the healing of damaged cartilage.

Referring to claim 7, Ek in view of Wen et al. discloses that as applied to claim 6. Ek further discloses a prosthesis wherein the alloy further comprises molybdenum (col. 25, lines 13-17).

Claims 10-15 lack an inventive step under PCT Article 33(3) as being obvious over Ek in view of Webster et al. in view of Schwartz et al.

Referring to claim 10, Ek in view of Webster et al. discloses that as applied to claim 9. However, Ek in view of Webster et al. does not show a prosthesis wherein human chondrocytes are disposed on a surface. However, Schwartz et al. teaches a prosthesis (22) (Abstract; Fig. 4) wherein human chondrocytes are disposed on a surface (lower 22) (col. 2, lines 6-12; col. 8, lines 41-48; col. 12, lines 29-60; Fig. 4). Therefore, it would be obvious to one of ordinary skill in the art at the time of invention to modify the invention of Ek in view of Webster et al. to include a prosthesis wherein human chondrocytes are disposed on a surface as taught by Schwartz et al. for the purpose of expediting the healing of damaged cartilage.

Referring to claim 11, Ek in view of Webster et al. discloses that as applied to claim 9. Ek further discloses a prosthesis further comprising molybdenum (col. 25, lines 13-17).

Referring to claim 12, Ek in view of Webster et al. discloses that as applied to claim 9. Ek further discloses a prosthesis having a portion consisting essentially of a cobalt chromium alloy (col. 25, lines 13-17).

Referring to claim 13, Ek in view of Webster et al. discloses that as applied to claim 9. Ek further discloses a prosthesis having a portion consisting essentially of a cobalt chromium alloy doped with molybdenum (col. 25, lines 13-17).

Referring to claim 14, Ek in view of Webster et al. discloses that as applied to claim 9. Ek further discloses a prosthesis comprising a screw (10) for insertion into bone (Fig. 1).

Referring to claim 15, Ek in view of Webster et al. discloses that as applied to claim 14. Ek further discloses a prosthesis comprising a first portion (40) including a contoured surface (42) of cobalt chromium alloy (col. 25, lines 13-17; Fig. 4c) and a second portion including a titanium screw (720') (col. 29, lines 45-47; Figs. 47, 48).

Claims 1-18 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under Article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the *PCT Applicant's Guide*.

In these Notes, "Article," "Rule" and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions, respectively.

INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report and the written opinion of the International Searching Authority, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only (see *PCT Applicant's Guide*, Annex B).

The attention of the applicant is drawn to the fact that amendments to the claims under Article 19 are not allowed where the International Searching Authority has declared, under Article 17(2), that no international search report would be established (see *PCT Applicant's Guide*, International Phase, paragraph 296).

What parts of the international application may be amended?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Preliminary Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

When? Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

Where not to file the amendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

How? Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet or sheets containing a complete set of claims in replacement of all the claims previously filed must be submitted.

Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively in Arabic numerals (Section 205(a)).

The amendments must be made in the language in which the international application is to be published.

What documents must/may accompany the amendments?

Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.

SEQUENCE LISTINGS AND TABLES RELATED THERETO IN INTERNATIONAL APPLICATIONS FILED IN THE U.S. RECEIVING OFFICE

The Administrative Instructions (AIs) under the Patent Cooperation Treaty (PCT), in force as of **July 1, 2009**, contain important changes relating to the manner of filing, and applicable fees for, sequence listings and/or tables related thereto (sequence-related tables) in international applications. The complete text may be accessed at <http://www.wipo.int/pct/en/texts/index.htm>.

Effective July 1, 2009, Part 8 and Annex C-*bis* will no longer form part of the AIs. Part 8 was introduced in 2001 as a temporary solution to problems arising from the filing of very large sequence listings on paper and provided for a *sequence listing forming part of the international application* to be filed in electronic form on physical medium (e.g., CD), together with the remainder of the application on paper. In 2002, Part 8 was expanded to include sequence-related tables and Annex C-*bis* was added to provide technical requirements. All applicants may now file complete international applications in electronic form, eliminating the need for these temporary provisions.

I. AIS PART 8 AND ANNEX C-BIS DELETED AS OF JULY 1, 2009

- A) **Sequence-related tables cannot be filed as a separate part of the description or in text format.** They must be provided as an integral part of the international application either:
- in PDF format as part of an international application filed in electronic form via EFS-Web; or
 - on paper as part of an international application filed on paper.
- B) **A *sequence listing forming part of an international application* may be provided either:**
- in electronic form, as part of an international application filed in electronic form via EFS-Web, in
 - Annex C/ST.25 text format (preferred), or
 - PDF format; or
 - on paper as part of an international application filed on paper.
- C) **A *sequence listing not forming part of the international application* (for search under PCT Rule 13ter) in Annex C/ST.25 text format**
- is not required where the *sequence listing forming part of the international application* was filed in Annex C/ST.25 text format as part of an international application filed in electronic form via EFS-Web
 - is required for search where the *sequence listing forming part of the international application* was filed in PDF
 - is required for search on physical medium (e.g., CD) where the *sequence listing forming part of the international application* was filed on paper as part of an international application filed on paper.

II. CALCULATION OF THE INTERNATIONAL FILING FEE AND FEE REDUCTION UNDER AI § 707

- A) **A sequence-related table** must form an integral part of the international application and will incur FULL page fees with no upper limit.
- B) **A *sequence listing forming part of an international application* filed:**
- via EFS-Web in Annex C/ST.25 text format will incur NO page fees;
 - on paper or in PDF format will incur FULL page fees with no upper limit.

III. AVAILABILITY OF SEQUENCE LISTINGS SUBMITTED FOR SEARCH UNDER PCT RULE 13TER

International Searching Authorities will be required to transmit to the International Bureau a copy of an Annex C/ST.25 text format sequence listing provided for search under PCT Rule 13ter. Any such sequence listing will be made available on PATENTSCOPE® (*sequence listings forming part of the international application* are already available).

IV. JULY 2009 REQUEST (PCT/RO/101)

The Request now has two options for the last sheet: one for paper filings; and one for EFS-Web filings. The July 2009 Request may be accessed at <http://www.wipo.int/pct/en/forms/index.htm>.